

Appln No.: 09/944,389
Amendment Dated: May 26, 2004
Reply to Office Action of June 20, 2003

REMARKS

This is in response to the Office Action mailed November 28, 2003 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Applicants request a three month extension of time for response and enclose the fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

Applicants thank the Examiner for taking the time to meet with their attorney on March 2, 2004. This paper will serve as Applicants' summary of that interview.

During the interview, the Examiner and Applicants' attorney discussed the rejection under 35 USC § 103 of independent claim 26 and the statement in the application that disposition of the labeled reagent on or within the macroporous body provided advantages over the disposition of the labeled reagent on or within the main porous carrier strip. A declaration was suggested to demonstrate this fact. Such a declaration is now enclosed, and a copy of the declaration with the color illustrations is being hand delivered to the Examiner.

This declaration supports the conclusion that devices in which the labeled reagent is provided within the macroporous body are superior to devices in which the labeled reagent is provided within the porous carrier. As reflected in Fig. 2 of the report attached to the declaration (Page 9), the intensity of the observable horizontal lines is more uniform and more reproducible in the 2 part constructs, even at lower concentrations of hCG. This same result is shown numerically in Fig. 4 (Page 11) based on optical density readings. At every concentration, the test line intensity was higher for devices using the two-part construct with the labeled reagent within the macroporous body.

In addition, as reflected in Fig. 3 (Page 10) of the report, the release of the labeled material is more uniform and controlled. There is no streaking of the reagent when the labeled reagent is provided in the macroporous body. In contrast, when the macroporous body is omitted, substantial streaking and irregular, uncontrolled release is observed.

The second issue discussed during the interview was support for claim 84 to the extent that it recites a capture reagent that is not expressly stated to be immobilized consistent with the description on Pages 1 and 2 of the specification. To address this issue, Applicants have amended claim 84 to include the recitation that "the capture reagent, the analyte and the labeled binding reagent form an immobilized complex in the detection zone when the analyte is present in the liquid sample applied to the device." This limitation clearly indicates the importance of the capture and immobilization within the detection zone, and is believed to be fully supported by the application, which discloses in multiple locations the formation of such a complex.


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To place the application in form for allowance, withdrawn claims 88 and 96-102 have been canceled without prejudice.

Claim 87 was also withdrawn from consideration. The Examiner pointed to the absence of a requirement for a housing in this claim as the basis for the restriction. Claim 87 has now been amended to include an express recitation of a housing. Accordingly, Applicants request that this claim be recombined with the other claims in this application. Applicants further point out that the part of the claim not in the Jepson preamble is the feature of having the labeled particulate reagent in a macroporous body, upstream from the porous carrier, which is the feature which is the subject of the declaration filed herewith.

In view of the foregoing, Applicants submit that all claims are now in form for allowance. Favorable reconsideration is respectfully urged.

Respectfully submitted,



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